

EXHIBIT P

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PHARMACEUTICALS NORTH AMERICA LLC,
VALEANT PHARMACEUTICALS INTERNATIONAL,
and VALEANT PHARMACEUTICALS INTERNATIONAL, INC.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

ALLERGAN USA, INC., and
ALLERGAN INDUSTRIE, SAS,

Plaintiffs,

v.

MEDICIS AESTHETICS, INC., MEDICIS
PHARMACEUTICAL CORP., VALEANT
PHARMACEUTICALS NORTH AMERICA LLC,
VALEANT PHARMACEUTICALS
INTERNATIONAL, and VALEANT
PHARMACEUTICALS INTERNATIONAL, INC.

Defendants.

Case No. 8:13-cv-01436 AG (JPRx)

DEFENDANTS' FINAL INVALIDITY
CONTENTIONS

1 Medicis Aesthetics, Inc., Medicis Pharmaceutical Corp., Valeant Pharmaceuticals
2 North America LLC, Valeant Pharmaceuticals International, Valeant Pharmaceuticals International,
3 Inc., and Galderma Laboratories, L.P. (collectively, "Defendants") by their undersigned attorneys,
4 submit the following Final Invalidity Contentions ("Invalidity Contentions") with respect to the
5 asserted claims of U.S. Patent Nos. 8,450,475 ("the '475 patent") and 8,357,795 ("the '795 patent") as
6 identified in Plaintiffs Allergan Industrie, SAS and Allergan USA, Inc.'s (collectively, "Allergan")
7 March 7, 2014 First Supplemental Disclosure of Asserted Claims and Infringement Contentions
8 Pursuant to S.P.R. 2.1 ("Infringement Contentions") and the February 9, 2015 letter from Elizabeth
9 M. Flanagan identifying the claims Allergan would be asserting.
10

11 Allergan has identified and asserted the following claims: 1, 2, 4-6, 8-9, 18, and 31-
12 37 of the '475 patent and claims 1, 3, 8, 11, and 41 of the '795 patent. These Invalidity Contentions
13 are based in whole or in part on Defendants' present understanding of Allergan's positions as set
14 forth in its Infringement Contentions, including any underlying interpretations of the claims by
15 Allergan.
16

17 Defendants' investigations are ongoing, as is fact discovery. Accordingly,
18 Defendants reserve the right to expand, add, change or otherwise amend their Invalidity Contentions
19 consistent with the Federal Rules of Civil Procedure and the Court's rules, based on their continued
20 investigation, fact discovery, expert discovery, and the Court's claim construction. Defendants also
21 reserve the right to amend their Invalidity Contentions based on any supplementation by Allergan of
22 its Infringement Contentions, or of its document production. Defendants also reserve the right to
23 amend their Invalidity Contentions based on any positions taken by Allergan as to the date of the
24 alleged invention of the asserted claims.
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DEFENDANTS' FIRST SUPPLEMENTAL INVALIDITY CONTENTIONS

I. Identification of Prior Art

Pursuant to the Court's Standing Patent Rules and in response to Allergan's Infringement Contentions, Defendants' identify the prior art in the following tables as either anticipating the asserted claims or rendering them obvious, individually or in combination with each other and other prior art. To establish the scope and content of the prior art, a motivation to combine or modify the prior art, or the knowledge and level of skill of those of ordinary skill in the art, Defendants may also rely on (1) non-prior-art patents, patent applications or publications, or other evidence (for example, the prosecution history files of U.S. and foreign patent applications) that may not qualify as prior art under 35 U.S.C. § 102, and (2) statements and admissions made by Allergan and its employees or agents in the patents-in-suit, during prosecution of the patents-in-suit or related patent applications, or in other documents.

The prior art references identified below are presumed to be enabled for all that they disclose. Defendants reserve the right to identify additional prior art evidencing enablement of these references should Allergan challenge the presumption of enablement. Moreover, Defendants reserve their right to assert that the claims of the '475 and '795 patents are indefinite under 35 U.S.C. § 112 and are invalid on other statutory bases after the Court issues a ruling on claim construction.

A. Prior Art Patents and Patent Applications

Patent Number	Country of Origin	Date of Issue or Publication	Abbreviation
WO 96/33751	Int. / FR	Oct. 31, 1996	<i>Debacker</i> ¹

¹ All citations to verified English translation provided herewith

Patent Number	Country of Origin	Date of Issue or Publication	Abbreviation
5,731,298	US / German	Mar. 24, 1998 (national phase of WO93/12801 (German), filed Dec. 24, 1992)	<i>Reinmuller I</i>
WO 2005/067944	Int. / German	July 28, 2005	<i>Reinmuller II²</i>
2005/0136122	U.S.	June 23, 2005	<i>Sadozai</i>
2008/0226724	U.S.	Sep. 18, 2008, earliest priority date Jan. 19, 2007	<i>Ji</i>
2006/0040894	U.S.	Feb. 23, 2006	<i>Hunter</i>
WO 2005/112888 A2	Int.	Dec. 1, 2005	<i>Wang</i>
2006/0194758	U.S.	Aug. 31, 2006	<i>Lebreton</i>
5,079,236	U.S.	Jan. 7, 1992	<i>Drizen</i>
6,521,223	U.S.	Feb. 18, 2003	<i>Calias</i>

² All citations to English equivalent, U.S. Patent No. 7,902,171

B. Prior Art Publications

Title	Date of Publication	Author	Publisher/Source	Abbreviation
"Effectiveness of next generation hyaluronic acid dermal fillers in the treatment of severe nasolabial folds"	Feb. 2007	Lupo <i>et al.</i>	Abstract of a poster (P2909) presented at the 65 th Annual Meeting of the American Academy of Dermatology, Feb. 2-6, 2007, in J. Am Acad Dermatol., 56(2) Supp 3, Feb. 2007, p. AB199	<i>Lupo</i>
"Volumetry: new opportunities for rejuvenating and modeling of your facial features"	Sep. / Oct. 2006	Ambroziak, Marcin	Ekspert, a magazine for customers clinic in dermatology and aesthetic medicine, plastic surgery, wellness and beauty spa (in Polish), September/October 2006 [with verified English translation] ³	<i>Expert Anti-Aging</i>
"Juvéderm: A Hyaluronic Acid Dermal Filler"	Nov. 2007	Monheit, Gary D. & Prather, Chad L.	<i>J Drugs Dermatol.</i> 6(11):1091-5, Nov. 2007	<i>Monheit</i>
"Preclinical evaluation of a novel hyaluronic acid 28 mg/ml, lidocaine 0.3% stable combination product"	Feb. 2007	Toth <i>et al.</i>	Abstract of a poster (P1039) presented at the 65 th Annual Meeting of the American Academy of Dermatology, Feb. 2-6, 2007, Washington, DC, in <i>J. Am Acad Dermatol.</i> , 56(2) Supp 3, Feb. 2007, pAB94	<i>Toth</i>

³ All citations herein to *Expert Anti-Aging* are made with reference to the English translation thereof

Title	Date of Publication	Author	Publisher/Source	Abbreviation
"Influence of various compounds on the degradation of hyaluronic acid by a myeloperoxidase system"	1994	Lindvall, Sven & Rydell, Gunilla	Chemico-Biological Interactions 90: 1-12 (1994)	<i>Lindvall</i>
"Injecting Puragen Plus Into the Nasolabial Folds: Preliminary Observations of FDA Trial"	Nov. 1, 2006	Kinney, Brian M.	Aesthetic Surgery Journal; 26: 741-748 (2006)	<i>Kinney</i>
Summary of Safety and Effectiveness of Cosmetic Tissue Augmentation product (CTA) [Eleveess]	Issued Dec. 20, 2006, Updated Jan. 10, 2007	FDA	Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p050033 , accessed Jan 2, 2014	<i>Eleveess Summary</i>

	Title	Date of Publication	Author	Publisher/Source	Abbreviation
1					
2					
3	"Effectiveness			Abstract of a poster	
4	and durability of a			(P1040) presented at the	
5	hyaluronic acid			65 th Annual Meeting of the	
6	28 mg/ml,			American Academy of	
7	lidocaine 0.3%	Feb. 2007	Hanke <i>et al.</i>	Dermatology, Feb. 2-6,	<i>Hanke</i>
8	stable			2007, Washington, DC, in	
9	combination			<i>J. Am Acad Dermatol.</i> ,	
10	product as			56(2) Supp 3, Feb. 2007,	
11	demonstrated in a			pAB94	
12	multicenter,				
13	randomized trial"				
14					
15	"The many ways	July 2007	Stern <i>et al.</i>	Biotechnology Advances	<i>Stern</i>
16	to cleave			25 (2007) 537-557	
17	hyaluronan"				
18					
19	"Heat-Induced	August	Bruskov <i>et</i>	Doklady Akademii Nauk,	<i>Bruskov</i>
20	Generation of	2001	<i>al.</i>	381 (2): 262-264, 2001	
21	Reactive Oxygen				
22	Species during				
23	Reduction of				
24	Dissolved Air				
25	Oxygen"				
26					
27	"Degradative	Feb. 16,	Šoltés <i>et al.</i>	Biomacromolecules 7:659-	<i>Soltes</i>
28	Action of	2006		668, 2006	
	Reactive Oxygen				
	Species on				
	Hyaluronan"				

Title	Date of Publication	Author	Publisher/Source	Abbreviation
"Stability of Lidocaine in Aqueous Solution: Effect of Temperature, pH, Buffer and Metal Ions on Amide Hydrolysis"	1987	Powell, Michael F.	Pharmaceutical Research, 4 (1): 42-45, 1987	<i>Powell</i>
"Thermal Stability of sodium hyaluronate in aqueous solution"	October 1994	Lowry, Karen M. & Beavers, Ellington M.	<i>Journal of Biomedical Materials Research</i> , 28:1239-1244, published 1994	<i>Lowry</i>
"Use of hyaluronic acid fillers for the treatment of the aging face"	Sep. 2007	Gold, Michael H.	<i>Clinical Interventions in Aging</i> , 2(3): 369-376 (2007)	<i>Gold</i>

C. Prior Art On Sale in the United States

Defendants identify the dermal fillers Restylane and Perlane, first approved by the FDA for sale by Q-Med AB in December 2003; Eleveess, first approved by the FDA for sale by Anika Therapeutics in December 2006; Juvederm 24HV and Juvederm 30HV, first approved by the FDA for sale by Allergan in June of 2006; and Puragen Plus, which was known and used in the US at least by 2006.

D. Additional Publications

Title	Date of Publication	Author	Publisher/Source	Abbreviation
"Hyaluronic Acid Fillers: A Comprehensive Review"	May 2009	Beasley <i>et al.</i>	<i>Facial Plastic Surgery</i> , 25(2):86-94 (2009)	<i>Beasley</i>
"Comparative Physical Properties of Hyaluronic Acid Dermal Fillers"	Feb. 2009	Kablik <i>et al.</i>	<i>Dermatologic Surgery</i> , 35 Suppl 1:302-12 (2009)	<i>Kablik</i>
"A prospective, split-face, randomized, comparative study of safety and 12-month longevity of three formulations of hyaluronic acid dermal filler for treatment of nasolabial folds"	July 2012	Prager <i>et al.</i>	<i>Dermatologic Surgery</i> , 38(7 Pt 2):1143-50 (2012)	<i>Prager</i>
"Volumizing effects of a smooth, highly cohesive, viscous 20-mg/mL hyaluronic acid volumizing filler: prospective European study"	2009	Hoffman, Klaud	<i>BMC Dermatology</i> , 9:9 (2009)	<i>Hoffman</i>

Title	Date of Publication	Author	Publisher/Source	Abbreviation
"Mentor Corporation Announces FDA Approval of Prevelle Silk"	March 21, 2008	Bloomberg News	Bloomberg News, available at http://www.bloomberg.com/apps/news?pid=newsarchive&sid=arVm09DtIA5c , accessed Jan 2, 2014	<i>Prevelle Announcement</i>
Excerpt of FDA Advisory Committee Briefing Document, Juvederm Voluma™ XC	May 2, 2013	Allergan	FDA	<i>Juvederm FDA Briefing</i>

II. The Prior Art Anticipates or Renders Obvious the Asserted Claims of the '475 and '795 Patents

Pursuant to the Standing Patent Rules and in response to Allergan's Infringement Contentions, Defendants set forth their contentions as to whether each of the identified items of prior art anticipate each asserted claim of the '475 and '795 patents and/or render the claims obvious. Citations to the prior art references are exemplary; other support for Defendants' Invalidity Contentions may be found elsewhere in the cited references. These charts and citations, at least in part, are based upon the positions taken by Allergan in its Infringement Contentions, without Defendants necessarily adopting the positions reflected therein. The identification of structure or processes in the prior art are not intended to necessarily reflect Defendants' claim interpretations, either directly or by implication.

The citations provided below and in the attached claim charts are representative of the teachings of the listed references. Defendants reserve the right to modify these statements and charts by adding additional prior art references to the extent such modification is appropriate in light of any

1 additional information gained through ongoing investigations or through discovery or in light of
2 amendments to Allergan's infringement contentions or other arguments made or positions taken by
3 Allergan.

4 **A. The Asserted Claims of the '475 and '795 Patents are Invalid under 35**
5 **U.S.C. § 103**

6 Defendants set forth below and in their claim charts in the attached Exhibits A and B
7 where each claim limitation of the asserted claims of the '475 patent and the '795 patent may be
8 found in the disclosed prior art references identified above, rendering the asserted claims obvious.
9 The claim charts and teachings of each of the listed references may be used in combination with
10 each other and with other references. Generally, the motivation to combine or modify the prior art
11 references may be found in the prior art references themselves, either expressly or impliedly, as
12 filtered through the knowledge of one of ordinary skill in the art; in common sense or common
13 knowledge; in the knowledge of those of ordinary skill in the art, taking into account the inferences
14 and creative steps that such a person would employ; in the prior art as a whole; and/or from the
15 nature of the problem to be solved. Moreover, all prior art identified above in I.A-C is in the same
16 field of endeavor: dermal fillers. Therefore, such a modification would be a routine arrangement of
17 known elements in a common field of endeavor, with each element performing the same function it
18 had been known to perform, yielding no more than what one would expect from such an
19 arrangement.
20
21

22 As disclosed in the '475 patent, HA based soft tissue fillers were known and under
23 rapid development since the FDA approval of the first HA-based soft tissue filler in December, 2003
24 ('475 patent, 1:63-65). HA crosslinked with each of four crosslinkers, i.e., 1,4-butanediol diglycidyl
25 ether (BDDE), divinylsulfone (DVS), 1,2,7,8-diepoxyoctane (DEO) and p-phenylene
26 bis(ethyl)carbodiimide (BCDI), had been used in approved soft tissue fillers for increased stability
27 and durability. Uncrosslinked HA had been commonly used together with the crosslinked HA to
28

1 reduce the extrusion force and ease the injection. More specifically, wrinkle fillers containing HA-
2 BDDE and uncrosslinked HA had been disclosed, such as Juvederm[®] Ultra (J24HV) and Juvederm[®]
3 Ultra Plus (J30HV) (*Lupo*), which contains HA-BDDE and at least 10% uncrosslinked or free HA
4 (see *Beasley*, Table 1); the two phase filler composition described in Example 2 of *Debacker*, which
5 contains HA-BDDE and 33% uncrosslinked HA; and the composition disclosed in *Reinmuller II*.
6 The crosslinked HA can have a mixture of high- and low-molecular weight HA (see *Lebreton*).
7

8 Pain is a barrier to cosmetic treatment. Lidocaine had been included in various filler
9 products to reduce the pain. Dermal fillers, such as Puragen[®] Plus, Eleveess[®] and Prevelle[®] Silk,
10 containing lidocaine and HA crosslinked with each of three different crosslinkers, DEO, BCDI and
11 DVS, respectively, had been approved and reported prior to August 2008 (*Kinney*, *Eleveess*TM
12 *Summary*, and *Prevelle*[®] *Announcement*). Puragen[®] Plus and Prevelle[®] Silk also contain
13 uncrosslinked HA, i.e., 6% and 2%, respectively. Preclinical and clinical studies had demonstrated
14 that dermal fillers containing crosslinked HA and lidocaine were stable, effective and durable (see,
15 e.g., *Toth* and *Hanke*). Indeed, a heat sterilized injectable gel containing a crosslinked HA and
16 lidocaine was described in a PCT application filed as early as Dec 24, 1992 (*Reinmuller I*, Example
17 1).
18

19 As a medical device to be injected into a human body, an HA filler must be sterile.
20 Heat sterilization or autoclaving had been used to sterilize almost any type of HA preparations
21 before 2008, crosslinked and/or uncrosslinked HA, with or without lidocaine (*Drizen*, 7:19-25;
22 *Lehreton*, Examples 3-4; and *Debacker*, page 14, lines 22-24 and Example 2; *Sadozai*, Example 12;
23 and *Reinmuller I*, Example 1). Although crosslinked or uncrosslinked HA may be subject to
24 degradation during autoclaving, the sterilized HA fillers can remain stable for months or even years
25 (*Drizen*, 7:44-46; *Lowry*, p1244).
26

27 The prior art reported that lidocaine stabilized HA. For example, *Sadozai*, a prior art
28 reference disclosed in the priority documents (e.g., U.S. Prov. App. No. 61/085,956 filed Aug. 4,

2008, 2:25 to 3:9), but omitted in the '475 patent, specifically teaches that "crosslinked HA with lidocaine can have good biostability, and can in some cases have a synergistic effect, increasing G' (the storage modulus)" (*Sadozai*, Example 21). This is consistent with the prior art teaching that adding free radical scavenger to an HA hydrogel decreases viscosity loss due to heat and/or storage (*Ji*, paras. [0061]-[0064]); lidocaine is a potent hydroxyl radical scavenger and singlet oxygen quencher (*Das*); and lidocaine was shown to inhibit HA degradation by the mechanism of hydroxyl radical (*Lindvall*). Moreover, in light of the court's claim construction ruling, stability requires the maintenance of only one property, including sterility, and is tied to no particular time frame.

More specifically, dermal fillers containing lidocaine and a mixture of HA-BDDE and at least 10% uncrosslinked HA (such as some Juvederm[®] products) had been disclosed in multiple prior art references before August 4, 2008 (see, e.g., *Reinmuller II* and *Hunter*).

Accordingly, as of August 4, 2008, the subject matter claimed in the asserted claims of the '475 and '795 patents was well known and obvious to a person of ordinary skill in the art..

B. The Asserted Claims of the '475 and '795 Patents are Invalid under 35 U.S.C. § 102

1. All of the asserted claims are anticipated by *Hunter*, *Sadozai*, and *Reinmuller II*

Hunter discusses the many uses of hyaluronic acid, especially when combined with other molecules. Restylane itself is mentioned by name multiple times. See, e.g., paragraph 0178. *Hunter* further notes that the composition (one example of which is disclosed to be Restylane) "may further comprise an anesthetic such as lidocaine[.]" Paragraph 0183. As Restylane-L[®] is merely the earlier Restylane compound with the addition of lidocaine, and as Restylane-L[®] is alleged by Allergan to infringe all of the asserted claims of the '475 patent, then the asserted claims are anticipated by *Hunter*.

Similarly, *Sadozai* describes a method for composing, stabilizing, and administering a stabilized hyaluronic acid composition. Within the specification, *Sadozai* specifically references

1 both Restylane and Perlane as examples when discussing this HA composition. Paragraph 0105.
2 *Sadozai* continues to note the benefits of incorporating lidocaine into such an HA composition,
3 including the benefit of increased stability. Paragraph 0107. Again, as Restylane-L® is merely the
4 earlier Restylane compound with the addition of lidocaine, and as Restylane-L® is alleged by
5 Allergan to infringe all of the asserted claims of the '475 patent, then the asserted claims are
6 anticipated by *Sadozai*.

7
8 *Reinmuller II* describes hyaluronic acid compositions to be used in the treatment of
9 inflammatory diseases, in particular skin diseases or mucous membrane diseases. The specification
10 of *Reinmuller II* notes that "[h]yaluronic acid is commercially obtainable in the crosslinked state
11 (e.g. ... Restylane from Q-Med). Col. 2, Ins. 21-26. *Reinmuller II* discloses that "[i]n addition to the
12 active compound hyaluronic acid, the pharmaceutical compositions according to the invention can
13 optionally also contain still further pharmaceutical active compounds which are compatible with
14 hyaluronic acid in the course of application, e.g. ... local anesthetics (of the lidocaine or novocaine
15 type). Col. 2, Ins. 54-63. Again, as Restylane-L® is merely the earlier Restylane compound with
16 the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe all of the asserted
17 claims of the '475 patent, then the asserted claims are anticipated by *Reinmuller II*.

18
19 2. Some asserted claims of the '795 Patent are anticipated by *Wang*
20 and the pre-mixing of lidocaine performed by practitioners

21 *Wang* teaches processes for preparing injectable HA gels that contain HA-BDDE.
22 Examples 1-7 of *Wang* are crosslinked HA gels that can include BDDE as a crosslinker. These gels
23 described by *Wang* are described as usable for "soft tissue augmentation". *Wang*, 2:1-4. *Wang*
24 additionally instructs the inclusion of anesthetics, such as lidocaine. *Id.*, 7:3-7. The gel was
25 sterilized via autoclaving. *Id.* at 7:23-24. As a result of these disclosures, *Wang* anticipates Claims
26 1, 3, and 8 of the '795 Patent.
27
28

1 Additionally, practitioners would pre-mix Restylane and Juvederm products with
2 lidocaine before injecting into their patients. These combinations produced a clinically viable filler
3 that remained sterile. This pre-mixing anticipates Claims 1, 3, and 8 of the '795 Patent.

4 3. Anticipation and Obviousness Charts

5 Charts providing more detail on the above-listed anticipation arguments as well as the
6 obviousness arguments for both the '475 and '795 Patents can be found attached.
7

8
9 Dated: February 17, 2015

PATTERSON BELKNAP WEBB & TYLER LLP

10 By: /s/ William F. Cavanaugh, Jr.
11 William F. Cavanaugh, Jr.

12 Attorneys for Defendants
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16 VALEANT PHARMACEUTICALS
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18 and VALEANT PHARMACEUTICALS
19 INTERNATIONAL, INC.
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PROOF OF SERVICE

I am employed in the County of New York, my business address is Patterson Belknap Webb & Tyler LLP, 1133 Avenue of the Americas, New York, New York 10036. I am over the age of 18 and not a party to the foregoing action.

On February 18, 2015, I caused a copy of the following document(s):

DEFENDANTS' FINAL INVALIDITY CONTENTIONS

to be served on the interested parties in this action by ELECTRONIC MAIL, via the email addresses set forth below:

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I declare under penalty of perjury that the above is true and correct. Executed on February 18, 2015, at New York, NY.

/s/ William F. Schmedlin
William F. Schmedlin